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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,536	06/29/2000	Earl A. Hubbell	AFFYP007X1C1	1335

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EXAMINER
FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/607,536	HUBBELL ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2003 has been entered.

Claim Rejections - 35 USC § 112

Claims 8-10 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new limitation in claim 8 and claim 24 which states “to the at least one of the polymer probes” is simply indefinite. While there is antecedent basis for this limitation, the claim limitation is not clear English. It is suggested that the word “the” be deleted and the word “said” be introduced in the place of the second "the" on the third line of the amendment, to read "at least one of said polymer probes that does not have the same actual sequence”.

Further, the term “lower hybridization” is indefinite because it is unclear what constitutes lower hybridization. Specifically, is this a reduced intensity of label, a reduced amount of hybridized material? What is lower?

Claim Interpretation

2. The central question posed by the amendment is what structural difference is imposed upon the substrate. The one clear structural difference is that the claim is not limited to the substrate with linked probes, but the claim now also encompasses labeled probes which are hybridized to the substrate. The other clear structural limitation is that at least one of the polymer probes must have a lower hybridization (intensity?) relative to some other probe. However, as will be noted in the response to arguments, while this amendment does impose some additional structure to the substrate, it does not distinguish from the prior art because the claim limitation regarding the term "control" targets is not given patentable weight. That is, the term "control" does not structurally distinguish one probe from another, so any probe which is linked to the substrate may be termed a "control".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8-10 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (U.S. Patent 5,837,832).

Chee teaches a substrate (column 6, lines 14-34, with nucleic acid probes coupled onto the membrane (see column 14, lines 14-34 and figure 26, for example) comprising:

a) a plurality of regions on the substrate in which diverse polymer probes are coupled in a checkerboard pattern, such as every overlapping 17 mer probe from exon 5 of the p53 tumor suppressor gene as well as four additional probes with each possible substitution at base 7 were also placed on the array (see figure 26 and column 23, lines 13-28) and,

b) a plurality of regions on the substrate in which the polymer probes having the same sequence are coupled and the array also clearly has many regions in which polymer probes having the same sequence are coupled, but where there are clearly sequences on the array that could bind to the same control monomer sequence but which are different in their actual sequence (see figure 26 and column 23, lines 13-28). For example, as shown in column 26, lines 45-50, when overlapping probes are made, they share all of their sequence but one nucleotide. Thus, the probes of Chee have probes which can bind to the same 16 mer target probe, since they share that entire region, but which differ in actual sequence. Further, as noted in column 23, Chee expressly also places additional probes with each possible substitution. For each probe, one of these four probes will be identical to the wildtype, yielding a situation where two identical probes are paired. Figure 27 makes this perfectly clear. In the first row, where

there is a T at the first position, the WT probe and the bottom probe would be identical, since both would have a T. There would be three different probes, which share 16/17 nucleotides, differing at position 7 with either an A, C, or G instead of a T. These would have been made with different monomer addition cycles and in any case, the products are not different however they are made.

Response to Arguments

5. Applicant's arguments filed November 6, 2003 have been fully considered but they are not persuasive.

Applicant argues that Chee does not teach a substrate with the labeled control targets which are hybridized in a way that results in a lower hybridization of one probe relative to other probes. This argument is not persuasive because it gives, as noted in the claim interpretation paragraph, too much weight to the term "control". As noted in the rejection, column 23 of Chee provides an example in which labeled probes (doubly labeled with fluorescein and biotin) were hybridized to the substrate which had four bound polymer probes that were identical except at one position. These labeled probes had a lower hybridization to three of the four bound polymer probes relative to the fourth bound polymer probe. This is exemplified in figures 26 and 27. So the hybridized array of Chee, as taught in Column 23, meets the new claim limitation. Therefore, the prior art rejection is maintained.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1634